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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/698,676 | 10/31/2003 | Martin T. Gerber | P0011666.00 | 1023 |

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| EXAMINER | |
|---|---|
| KASZTEJNA, MATTHEW JOHN | |
| **ART UNIT** | **PAPER NUMBER** |
| 3739 | |
| **MAIL DATE** | **DELIVERY MODE** |
| 10/31/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/698,676 | GERBER ET AL. | |
| | Examiner | Art Unit | |
| | Matthew J. Kasztejna | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 11, 2007 has been entered.

### *Notice of Amendment*

In response to the amendment filed on June 11, 2007, canceled claims 1-26 and new claims 27-47 are acknowledged. The following new grounds of rejection are set forth:

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27, 36-37 and 46-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-24 of copending Application No. 10/698,213. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims involve an obvious broadening of the claims in application serial no. 10/698,676.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-32, 34, 36-43 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,486,161 to Lax et al. in further view of U.S. Patent No. 7,037,294 to Luther et al.

**In regards to claims 27, 30-32, 34, 36-37, 41 and 46-47,** Desai discloses a system for delivering a denervating agent to a prostate gland comprising: an imaging apparatus 302 sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole; a needle positioned through the hole of the imaging apparatus for insertion through a rectal wall

of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen, wherein the needle is capable of extending out of the imaging apparatus parallel the long axis of the imaging apparatus (see Col. 19, Line 67 - Col. 20, Line 11 and Fig. 25). Furthermore, Desai discloses a method of localized fluid therapy (see Col. 19, line 57 – Col. 20, Line 51). Desai disclose an apparatus wherein a slidable portion 338 is responsible for extending and retracting a needle 306 into tissue but is silent with respect to a spring-loaded needle and wherein actuating a spring mechanism to cause the distal end of the needle to be inserted into the prostate gland. Lax et al. teach of an analogous medical probe having a cutting cannula 84 which is spring-loaded in a retracted position and wherein a release tab 108 is pushed down to move the cannula forward when desired. It would have been obvious to one skilled in the art at the time the invention was made to include a spring-loaded needle in the apparatus of Desai to allow for more efficient and effective actuation of the needle into tissue as taught by Lax et al. Desai and Lax et al. are silent with a wheel used to rotate the orientation of the needle. Luther et al disclose a needle having a wheel which permits rotation of the needle to a desired orientation. It would have been obvious to one skilled in the art to have further modified Desai and Lax et al. such that the spring-loaded needle includes a wheel to rotate the needle to a desired orientation. Such a modification allows to needle to be located more precisely in the target tissue as desired. The modified device of Desai and Lax et al. would be capable of permitting rotation of the needle while in the shaft.

**In regards to claims 28-29 and 45,** Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the imaging apparatus comprises an ultrasonic imaging apparatus and is inherently capable of comprising a hyper-echoic coating as is well-known in the art (see Col. 19, Lines 64-67).

**In regards to claim 38,** Desai discloses a system for delivering a denervating agent to a prostate gland, further comprising a denervating agent delivery 348 assembly coupled to the needle to deliver the denervating agent through the lumen (see Col. 17, Lines 18-57).

**In regards to claims 39-40,** Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery system assembly 348 includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen. As can be seen in Fig. 25 the second actuator comprises a plunger as well as a hub and a fluid line for attachment of the reservoir to the needle (see Col. 17, Lines 53-55).

**In regards to claims 42-43,** Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery assembly 348 includes a first reservoir to hold a substantial amount of the denervating agent, a second reservoir to hold a discrete dose of the denervating agent, and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator (see col. 20, Lines 51-

65, and Col. 21, Lines 18-30). Syringe 348 is interpreted to be the first reservoir and the lumen of needle 306 is interpreted to be the second reservoir.

Claims 33, 35 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,486,161 to Lax et al. in further view of U.S. Patent No. 7,037,294 to Luther et al. in further view of U.S. Patent No. 6,365,164 to Schmidt.

**In regards to claims 33, 35 and 44,** Desai, Lax et al. and Luther et al. disclose a system for delivering a denervating agent to a prostate gland but are silent with respect to the denervating agent including botulinum toxin. Schmidt teaches methods for treating neuronally-mediated urologic and related disorders and more particularly, benign prostatic hyperplasia (BPH), by administering a composition that includes at least one neurotoxic compound. Such a neurotoxin can be botulinum toxin type A (see Col. 4, Lines 3-29). It would have been obvious to one skilled in the art at the time the invention was made to use a composition including botulinum toxin type A with the device of Desai, Lax et al. and Luther et al. in order to help more effectively treat BPH as taught by Schmidt.

***Response to Arguments***

Applicant's arguments with respect to claims 27-47 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK

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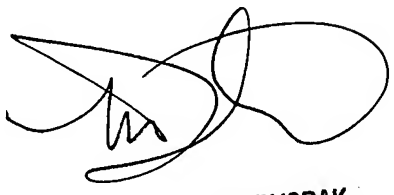

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